

Said G. Osman M.D.
52 Thomas Johnson Drive
Frederick, MD 21702

EXHIBIT C

Dear Dr. Osman,

Thank you for meeting Brian and I for dinner last night and for sharing your ideas for a dynamic anterior cervical plate. I apologize that this is an area where I cannot give you an immediate answer. We have been pondering a project of this type for some time and have been hesitant to get started due to questions regarding the efficacy of the dynamic concept. As I stated last night, we expect to make a decision at our advisory meeting in

Most of the problems with dynamic plating that I am familiar with have more to do with the plate design, than the dynamic loading as a concept. I would also add that we agree on the potential solution of a telescopic plate to avoid impinging on adjacent levels, and that subsidence needs to be controlled to a prescribed amount, however the problem of "how much" is huge (and unsolved). I don't think an educated guess will do. Finally unidirectional loading is a very intuitive concept. I'm willing to bet that any company that has done one of these plates would have chosen this option if they could have solved these problems:

- The ratchet concept requires that either the male or female piece flex, or deflect, enough to move from tooth-to-tooth, without breaking off teeth or otherwise causing metal debris. And, elastic enough to "spring back" as it deflects. Yet it must be stiff enough to resist normal loads. These requirements may be mutually exclusive.
- Certainly any construct that is not rigidly fixed will be less stable as compared to a solid plate. I think it will be very difficult to maintain stability in the other degrees of freedom when we have the design intent of this feature including enough elasticity to solve the first problem! Particularly in lateral bending and axial rotation. Stresses in these directions can be proportionally high in the cervical spine. I happen to believe that most cervical non-unions are unstable in rotation first, and only show up on flexion extension films because that is how we look at them!
- I am concerned that the unidirectional nature would increase load on the graft. This may be easy to determine through experimentation, but what do we do with the information? Maybe a little increase is good?
- Will the patient feel the clicking as the plate moves from tooth-to-tooth? (A rather uncomfortable feeling I would suspect?)
- What is the rationale behind the increments – as little as possible? If so it will take considerable development time and experimentation to determine what this is.

The material properties present the biggest problem because we do not have a lot of materials to choose from. We should probably try titanium first, but it does not have the best properties when you want it to act like a spring. All of these requirements will certainly drive up manufacturing costs substantially as they require high degrees of precision in order to perform reliably.

So is it worth it? If rigid, or semi rigid plating works 100% of the time (OK call it 98%) for one or two level ACDF's, and everyone agrees that it would be a stretch to apply this concept to three or more segments, what problem have we solved?

These are all legitimate questions that need to be answered before we commit to a project like this. I would appreciate any further thoughts you have on the subject – especially prior to our June advisory meeting. Brian and I discussed asking you to visit our plant in Austin. If you have the time I think it could be very worth while, and give us a chance to talk through these issues further.

Thank you for your interest in our company.

Sincerely,



Erik Wagner
V.P., Research and Development
Spinal Concepts, Inc.

cc: Brian Smith, sales representative
Colleen Turner, product manager - cervical products